REMARKS

Claims 1 and 12 have been rejected under 35 USC §103(a) as being unpatentable over EP 0952171 in view of '893 and in further view of US 5149747 in an earlier Office Action and that rejection is maintained in the present Office Action. The Examiner contends that EP '171 does not require the copolymer to be in a liquid state as asserted by the Applicant, but rather, references hydrogels which may be employed as stent coating. However, Applicant continues to assert that the teachings of EP '171 cannot be used against the instant invention with or without the teaching of '747. First, the liquid polymers of '171 are expected to form hydrogels upon contacting wet biological tissue, as in the case of a vascular wall. Therefore, the active compositions applied onto the stent are to be liquid and packaging a liquid-coated sterilized stent prior to use is obviously impractical since the liquid coating cannot be maintained in a uniform state on the surface of the stent. This is quite different from a pre-formed solid coating that is already present on the stent before application. In essence, the deployment of a liquid-coated stent, as per the existing clinical techniques, without affecting the amount and position of coating on the stent is practically impossible. Also, during the hydrogel formation in accordance with EP '171, in the biological environment, part of the drug therein diffuses to the application site and the concentration of the drug remaining in the hydrogel will decrease. This is different from the solid coating of the instant invention where the drug concentration in the coating remains intact during and shortly after the deployment of the coated stent. The release profile of a drug from a non-uniform

hydrogel coating will be associated with unpredictable and non-uniform initial burst, particularly if the system contains at least two drugs as is the case in the instant invention where the drug release profile will be steady with no unpredictable initial burst. Further, the use of U.S. 2002/0091433 and U.S. 2003/0083740 to support the Examiner's rejection is unfounded, first, because US '433 is directed to a crosslinked, non-absorbable hydrogel stent coating, wherein the crosslinking is a key feature needed to maintain the hydrogel on the surface of the stent. This is different from the solid linear (non-cross-linked) absorbable coating of the instant invention. Furthermore, the citation of U.S. 5,304,121 in '433 is irrelevant as '121 is directed to the deployment of the hydrogel and does not call for its use as a coating on a stent. Also, U.S. '740 discloses a coating composition having a melting temperature of 50°C or less wherein the composition of the polymeric coating is selected from a group of polymers which does **not** include the solid, segmented polyether-esters of the instant invention. Accordingly, it is requested that the Examiner reconsider and withdraw the present rejection.

Claims 1, 8 and 12 have been rejected under 35 USC §103(a) as being unpatentable over EP '171 in view of US '747 and in further view of U.S. Patent No. 5,681,846. The Examiner argues that EP '171 discloses hydrogel polyester copolymers and their utility in providing a protective barrier to prevent post-surgical adhesion, etc., but fails to disclose introduction of at least one carboxyl side group by free-radically achieved maleation, which is taught by '747, and fails to disclose an antineoplastic drug such as paclitaxel, which is taught by '846. However, the irrelevance of '171 has been argued above. Consequently, the teaching of '846 on paclitaxel delivery in matrices,

which are totally unrelated to those of the instant invention, makes the use of '846 in conjunction with '171 equally unjustified. As to the '747 disclosure of the use of maleic anhydride to acylate the polymer, this is also irrelevant to the teaching of the instant invention. It should be noted that the use of maleic anhydride in the present invention leads to inserting a succinic acid residue into the polymer chain through a free radical reaction entailing the creation of a new C—C bond and not a C—O bond as is the case in '747. Accordingly, it is requested that the Examiner reconsider and withdraw the present rejection.

Claims 1, 8, 12 and 17 – 18 have been rejected under 35 USC §103(a) as being unpatentable over EP '171 in view of US '747 in further view of US '846, in further view of US 5304121. The Examiner argues that the primary reference and the first two secondary references teach the present invention but fail to teach a metallic endovascular stent coated with the hydrogel composition, which is taught by US '121. However, as arguments are present above over the first three references, it is submitted that the addition of US '121, which does address metallic stents, in no way obviates the present invention. Rather, it is asserted that, while the Examiner was able to assemble these four references based on the hindsight gained from a review of the present specification, no combination of the four anticipates or renders obvious the present invention. Thus, is it requested that the Examiner reconsider and withdraw the present rejection.

Accordingly, it is submitted that the present application is in condition for allowance and such action is respectfully requested.

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